# CAP OPERATED RETRACTABLE MEDICAL DEVICE

## BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention pertains to a retractable medical device which in the preferred embodiment is useful for collecting body fluids from a patient. It is primarily useful as a blood collection device.

2. Background of the Prior Art

Prevention of needle sticks has become a paramount concern of the healthcare industry because of serious and deadly risk factors associated with AIDS and other serious communicable diseases. Blood collection devices utilize a needle inserted into a patient's vein so as to draw blood through the needle into an associated separate collection reservoir. Accidental needle sticks from previously used needles can occur during the fluid withdrawing process and subsequent handling and disposal operations. Until such used medical devices are destroyed, they remain potentially lethal.

Illustrative of the type of device used for blood sampling is a collection device sold under the trademark Vacutainer® by Becton Dickinson Corporation, which has been the conventional standard for this type of device. It has a tubular syringe-like body with a needle in the front end, part of which extends back into a tubular syringe-like shell. Part of the needle extends externally for puncturing the skin. An evacuated collection tube with a rubber stopper is placed into the open back of the syringe-like shell with the rubber stopper against the internal end of the needle. After the skin is punctured, the collection tube is pushed forward to cause the needle to enter the evacuated tube. Vacuum helps draw blood into the collecting tube. When a sufficient sample has been obtained, the collecting tube and the stopper are simply withdrawn from the tubular shell and sent to the laboratory. This particular device has a permanently extended needle and an opening in the back for the collection tube which remains open after the collection tube is removed, leaving small quantities of blood and an internally exposed needle.

Retractable medical devices which are used for collecting fluid samples from patients are known. While they offer retraction of the needle, they suffer from high manufacturing and assembly cost. They lack simplicity which results in a multiplicity of difficult to manufacture and assemble parts. An early example of such a device is Haber U.S. Pat. No. 4,813,426 which employs a mechanically translatable insert holding a double-ended needle. It has a position which compresses a spring portion of the holder. When buttons extending from opposite sides of the outer tube are compressed, the needle carrier can be mechanically moved to the position of use or to a rearward safe position. Allard U.S. Pat. No. 4,838,863 describes a spring loaded double ended needle carrier in a T-shaped housing having an opening behind for the sample tube. The needle holder is locked in a use position with a removable pin which is withdrawn to retract the needle. Alternately, breakable tabs on the needle holder extend laterally under a shelf with pins which may be pushed down when the sample tube is inserted to fracture the breakable tabs thereby releasing the needle holder which is withdrawn into the interior as the sample tube is removed. Subsequently, a cap is provided to close the back. Allard does not explain how one could assemble the device without making the outer body in two or more pieces.

In addition, a number of devices attach the double ended needle to a partially withdrawable plunger with an opening

in back for the sample tube. Shaw U.S. Pat. No. 5,423,758 discloses a tubular outer body with a partially removable plunger. The plunger has a separable needle holding portion for a double ended needle and an opening in the back of the plunger for a sample tube. It utilizes a two position end cap from which the sample tube extends. The plunger is used to position and retract the needle assembly.

By in large, the prior art fails to take into account the need for a single one-handed required and controlled action that will simultaneously close the back of the main body of the device and initiate retraction of the exposed needle after the sample tube is removed. If the inner needle which punctures the collection tube is not covered with a rubber sheath, blood will continue to flow into the device. This blood provides a source of contamination during subsequent handling of the device. If the internal needle is covered with a rubber sheath to prevent the blood from continuing to flow after the collection tube is removed, the rubber sheath serves to hide a sharp needle which can result in unintended punctures. Since the sheathed needle looks safe, people tend to put their finger into the open end without thinking. Even if a cap were to be provided, it use requires a separate operation and it is easy to forget or simply fail to use it. Consequently, an improvement in safety is possible with a device that caps the back of the device while it is retracting.

## SUMMARY OF THE INVENTION

The invention is a retractable medical device in the form of a blood sampler which can be operated by one hand without removing the device from the patient after one or more collection tubes are filled. While one hand holds a gauze pad over the puncture site, the other hand is used to manipulate a cap hingedly connected to the back of the device. As the cap is moved to the closed position, it moves a movable member forward releasing a retraction body with the needle which is retracted entirely within the walls of the now closed body. Once retracted, the sharp double ended needle is confined and cannot be used. Safety is assured because the act of closing the cap is the same act which causes retraction of the needle. It is the only way retraction can take place.

The cap operated retractable medical device includes a long thin walled tubular outer body having a back end with an opening and a front end which incorporates a centered hub which provides an opening for a needle holder. A long thin walled tubular movable member closely fits entirely within the outer body. The movable member has a back end with an opening and a front portion wherein the front portion has a radially enlarged inner surface and an outer surface. A retraction body having a disk-like laterally extending wall with an outwardly facing edge is releasably held within the movable member at a forward position by means of cooperation between the radially enlarged inner surface of the front portion of the movable member and the outwardly facing edge.

A thickened or stepped in portion of the wall of the outer body is provided for a short distance behind the front wall. The hub, preferably in the form of an annular ring, serves as a stop for the retraction body spaced behind the front wall of the outer body. It also serves to hold the front end of the compression spring which is placed between the front wall of the outer body and the retraction body. The movable member is held in position within the outer body, with the retraction body adjacent the hub, by means of a tight area created between the outer surface of the movable member and the stepped in or thickened inside surface of the wall of

the outer body near its front end. The retraction body carries a double ended needle.

A cap which is hinged at the back end of the outer body is selectively movable between an open position and a closed position relative to the opening of the back of the outer body. The cap includes a cam surface configured to engage the back end of the movable member inside the outer body and move it forward as the cap is moved to the closed position. Closing the cap causes the movable member to move forward while the retraction body is restrained by the hub in the outer body thereby releasing the retraction body from the movable member. A spring compressed under the retraction body expands to drive the retraction body and double ended needle backward within the movable member just as the cap is fully closed. Another stepped in portion of the wall of the movable member near the back end catches the retraction body before the needle behind the retraction body can reach the area of the cap.

The tight area between the outer surface of the movable member and the inner surface of the outer body near the front of the device is in the nature of an interference fit which still allows the movable member to go forward when the cap is closed. Since the forwardly extending needle of the blood sampler does not need to puncture a rubber seal as does a syringe, the retraction body and movable member do not have to resist large forces before releasing. The rearward facing portion of the needle in the device does have to puncture the seal of a collection tube, but since the retraction body is positioned against a hub or stop at the front of the outer body and cannot move forward, impaling the collection tube on the interior end of the needle cannot disassociate the retraction body from the movable member.

The needle holder is carried by the retraction body with the needle extended in both directions. In the assembled condition, the conjunction of the retraction body and the hub provide a convenient means for installing the already assembled needle holder and needle through the opening in the front wall of the outer body. The needle holder is threaded into a centrally located opening in the retraction body. The centrally located opening of the retraction body has a forwardly extending tubular wall which cooperates with the hub to confine the spring between the hub and the retraction body. Since the spring closely circumscribes the tubular wall of the retraction body, it serves to stabilize the retraction body so that it tends to move straight back without tilting during its retraction.

The cap has an outer rim larger than the opening at the back of the outer body and an inner rim containing one or more camming protrusions which cam the back of the movable member when the cap is closed. The inner rim preferably comprises two camming protrusions which are spaced apart and positioned to enter the opening when the cap is moving to the closed position. The protrusions are oppositely positioned along the inner rim about half way from the hinged connection. The protrusions actually contact the back of the movable member before the cap is closed and continue moving the movable member until retraction occurs just as the cap is becoming fully closed.

A fail-safe design is provided. The needle can only retract when the cap is closed. Since the cap is hinged to the device, it cannot be lost or misplaced. There is little chance of premature retraction since retraction can only be initiated by closing the cap. Even if retraction is forced by pushing the needle against a solid object, the needle does not come out of the body. Once the cap is closed to retract the needle, no special handling is required. A sound is made when the

retraction occurs. The fact that the cap is closed together with the sound assures that the needle is no longer exposed, even without looking. An additional visual indication is also provided by the clear plastic walls of the outer body and movable member which enables the user to visually observe the extended spring that proves retraction has occurred.

The parts are fewer in number than other retractable devices comprising only an outer body which can be molded as one together with the cap, the movable member, the retraction body and the needle assembly. Due to the fact that the movable member is contained entirely within the outer body, a more compact device is made possible, limited in length only by the space required to enclose the double ended needle. The parts are suitable for fabrication in multiple cavity high speed plastic injection molding machines. No special materials are utilized apart from the usual plastic materials employed in the syringe industry.

Assembly is simplified by sliding interference fitting of the parts in a straight line direction. First the retraction body is inserted from the rear of the movable member and moved forward to fit within its mouth. The back end of the compression spring is placed over the tubular extension and into a spring groove of the retraction body while the other end is dropped into a hub at the front of the outer body as the movable member is moved forward to compress the spring. Then the movable member is moved forward until the front end slidingly engages the stepped in portion of the outer body which creates a tight area where the movable member is held and the retraction body is positioned just above the hub which serves as a stop. The needle assembly is then screwed into the retraction body through the opening in the front wall of the outer body. A removable protective cap can be placed over the exposed needle until the device is ready for use.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cut-away view on the center line of the assembled medical device in the form of a blood collection sampling device in the ready-to-use position without the collection tube in place;

FIG. 2 is a view of the device of FIG. 1 after the cap has been moved from the open to the closed position thereby triggering retraction of the retractable member and closing the rear of the outer tube;

FIG. 3 is a perspective view of the outer tube and cap with the movable member in place in the position of use;

FIG. 4 is a front view of the medical device of FIGS. 1–3 showing the back of the cap when it is laid out level with the plane of the flange at the back of the device;

FIG. 5 is a plan view of the retraction body seen from behind looking forward towards the front of the device;

FIG. 6 is a view of the retraction body of FIG. 5 cut-away on the line 6—6 of FIG. 5;

FIG. 7 is a partially cut-away view of the movable member showing preferred details of the wall structure.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The medical device is generally referred to by the reference numeral 10 in FIG. 1. The device 10 is a fluid collection device, more particularly a blood sampler. Device 10 has an elongated body 12 having a partially closed front 14 and an open back 16. There is an intermediate wall portion 18 connecting front 14 and back 16. Intermediate wall portion 18 has an outer wall surface 20 and an inner wall surface 22

which defines a hollow interior 24. Inner wall 22 together with open back 16 forms opening 26 at the back of outer body 12. A flange 17 is positioned at the back of outer body 12 to serve as a grip. It may be noted that flange 17 could be moved forward along body 12 if desired and is not necessarily located at the back of body 12. In this regard, the forward direction is the direction in which the external needle 88 is extended.

FIG. 4 is a front view of elongated body 12 of FIG. 3 showing the flange 17 at the back and a hub 28 having a chamfered opening 86 in front. A selectively positionable cap designed to close opening 26 generally referred to by reference numeral 30 is hingedly connected at hinge 32 to back 16 of body 12. FIG. 4 shows cap 30 having a solid back 31. It is shown laid out fully from the position of FIG. 3.

Cap 30 is positionable between an open position as shown in FIG. 1 and FIG. 3 and a closed position as shown in FIG. 2. The open position allows access to hollow interior 24 while the closed position blocks opening 26 from outside access. Cap 30 has an outer rim 34 larger than opening 26 in the back of outer body 12 and an inner rim 36 which constitutes a camming protrusion which moves through opening 26 when the cap is moving to the closed position. The preferred form of the inner rim is two camming protrusions 38 which are spaced apart and positioned to enter opening 26 close to inner wall surface 22 when the cap is moved to the closed position. The preferred protrusions are oppositely positioned along the inner rim about half way from hinged connection 32. Protrusions 38 could take different forms. As will be seen, they are designed to operate the movable member. FIG. 3 shows the orientation of body 12 as it would be placed above a patient's arm during use. The lobes of the protrusions of this preferred arrangement are not in the way of a conventional collection tube which will be inserted from the rear. The collection tube slides between the protrusions into opening 24. This means that cap 30 does not require an open position more open than a right angle with respect to back end 16. An additional advantage is that the cap closes more fully before it contacts the movable member and contacts it at opposite points which avoids any tendency to bind. The outer surface of inner rim 36 friction fits into opening 26 so that the cap stays closed.

An elongated movable member generally designated 40 in FIG. 1 is shorter than outer body 12 and is contained entirely therein. Movable member 40 is a long thin walled tubular member having a wall 42 with an external surface 44 and an internal surface 46. Wall 42 is configured to define the external surface 44 in close proximity to inner surface 22 of outer body 12. The wall and internal surface 46 define a cavity 48 therethrough and an open back end 50 which serves as a contact surface for one or more camming protrusions 38 on cap 30. Open back end 50 defines an opening 52, which as will be seen, accepts a conventional evacuated collection tube with a rubber stopper in front, not shown in the Figures. The collection tube occupies most of cavity 48 and its closed back end extends some distance beyond back 16.

Referring now to FIG. 7, movable member 40 has a front end portion 54 which preferably has a radially enlarged inner surface 56 and an outer surface 58 which may also be radially enlarged as shown. It has a front end 59. A retraction body 60 seen in FIGS. 5 and 6 is releaseably held by movable member 40 at the radially enlarged inner surface 56 of front end portion 54.

Retraction body 60 is best seen in FIGS. 5 and 6. Retraction body 60 has a laterally extending wall 62 in a

disco. ape with an outwardly facing edge 64 which i. held by the radially enlarged inner surface 56 of wall 42 as shown in FIG. 1. The radially enlarged surface 56 need not be a continuous surface, although that is preferred. It could be radially enlarged sectors or lands which project inwardly from inner surface 46 sufficient to hold retraction body 60 during use. There is no need for a seal at edge 64.

Retraction body 60 further includes a forwardly extending tubular wall 66 having a centrally located opening 68 which extends longitudinally along the central axis of the assembled device. Longitudinally extending opening 68 has an inner wall surface 70 which may have threads or a plurality of angularly spaced sets of radial protrusions 72. Radial protrusions 72 can serve as a thread substitute for securing a threaded needle holder 74 best seen in FIGS. 1 and 2. A spring groove 76 is formed around tubular wall 66 to receive the end portion of a spring 77. The front of retraction body 60 is designated 78 as a transition zone which connects tubular wall 66 with laterally extending wall 62. An angular extension 80 between front 78 and wall 62 provides an offset for wall 62 behind front 78 in the vertical direction such that compressive force applied to edges 64 can cause flexing of angular extension 80. Angular extension 80 can act somewhat like a very stiff spring especially if radial slots 82 are provided at one or several locations through wall 62. Such slots are indicated schematically by dotted lines in FIG. 5 as radial slots 82. A number of such slots could divide discoid wall 62 into sectors which are slightly compressible toward the center, independently of each other. This could facilitate fitting retraction device 60 within front portion 54 of movable member 40.

Returning to FIGS. 1 and 2, it can be seen that hub 28 has a flanged wall portion 84 which extends forwardly from wall 14 and forms an opening 86 for threaded needle holder 74. In addition, wall portion 84 extends rearwardly behind front 14 to form a stop 86. Needle holder 74 has a portion which extends forwardly of hub 28 and a threaded portion behind which screws into opening 68 of retraction body 60. Double ended needle 88 is securely held extending forwardly and rearwardly from needle holder 74. A collapsible rubber sheath 90 sealingly covers the rearwardly extending portion of needle 88. It is designed to seal the flow passage through needle 80 after a collection tube is removed in preparation for collection of another sample in a second collection tube. Stop 86 constitutes a means for preventing forward movement of retraction body 60 which is spaced behind the back of front wall 14. Stop 86 is preferably an annular ring which is a rearward extension of wall 84 behind wall 14. Stop wall 86, together with the inwardly extending flanges of wall 84 which form opening 86, create a well for holding spring 77.

The radially enlarged surface 58 of front end portion 54 of movable member 40 is slidably held by a portion of inner surface 22 of outer body 12 at a location spaced behind partially closed front wall 14 of the outer body. Intermediate wall 18 has a thickened portion 92 which extends a short distance behind front wall 14. This creates an inner surface portion 94 which extends radially inwardly from inner surface 22 of intermediate wall 18. This creates a constricted area in a band around the inside of outer body 12 adjacent front wall 14. A smooth ramp 96 leads into thickened area 92 whereby movable member 40 can be moved forwardly until outer surface 58 slidingly engages surface 94 thereby creating a tight area in a band between surfaces 58, 94 which holds movable member 40 in the position shown in FIG. 1. The tight area is a sliding interference fit between the front portion of the movable member and the inner surface of the outer tube. Alternately, thickened area 92 could be a plurality

of angularly arranged land areas which c : portions of outer surface 58. A great degree of holding force is not needed since the front portion of needle 88 is primarily designed to puncture skin and is not normally used to pass through rubber stoppers commonly used in vials.

Thickened area 92 may be regarded as creating a stepped in portion on the inner surface of body 12 which cooperates with outer surface 58 of the front portion of the movable member to create the tight area whereby the movable member is held in its forward position shown in FIG. 1. The stepped surface creates a smaller diameter for a short distance behind front wall 14 which clamps radially enlarged outer surface 58 when the movable member is introduced through opening 26 and moved forward until the cooperating surfaces 58 and 94 slidingly engage. Some compressive force is directed around the mouth of member 40 toward retraction body 60 which is held inside. The forwardly extending tubular wall 66 in cooperation with hub 28 serves to confine biasing spring 77 between the hub and the retraction body. The flanged wall portion 84 forms the opening 86 for needle holder 74 which is smaller than the diameter of the spring. Flanged portion 84 thus supports the spring at its forward end. In its use position in FIG. 1. the surface 63 of retraction body 60 wall 62 lies closely adjacent to stop 86 A plurality of guide bumps 102 on wall surface 22 help stabilize and locate movable member 40 within outer body 12 as it moves.

Assembly of device 10 is simple and well suited for automated assembly. First retraction body 60 without the needle holder is pushed through the open back end of movable member and moved forward with a tool until cooperating edge 64 and inwardly facing surface 56 are engaged at the mouth of movable member 40. The back end of spring 77 is positioned circumscribing tubular wall 66 of retraction body 60 and the front of the movable member holding the retraction body and the spring are pushed into opening 26 at the back of outer body 12. The front end of spring 77 is seated into a well-like opening 104 within hub 28 at the front of the outer body. A tool may be inserted through opening 86 to serve as a guide for the spring as it moves forward and prevent lateral buckling of the spring as it is compressed. Movable member 40 is moved entirely within outer body 12 until the outwardly facing surface 58 engages the cooperating stepped in surface 94 and moved forward until surface 63 of the retraction body reaches stop 86. Threaded needle holder 74 together with needle 88 is then placed into opening 86 and turned to secure it in place in retraction body 60. Finally. a removable protective cap (not shown) is placed over the exposed portion of needle 88 and device 10 is ready for sterilization and packaging.

In operation. the cap operated retractable medical device is supplied as shown in FIG. 1 except that a conventional removable cap is placed over the extended needle with its back end frictionally held by the protruding portion of needle holder 74. The protective cap is removed and needle 88 is inserted into a vein. A conventional rubber stopper collection tube (not shown) is inserted into the open back of device 10 and pushed forward while holding device 10 until the rearwardly extending portion of needle 88 punctures the rubber stopper and the needle passes through rubber sheath 90. The outer tube is held while a blood sample is collected in the collection tube. When the collection tube is filled sufficiently. it is removed from device 10 and put down. Sheath 90 restricts further flow of blood. Typically. a gauze pad is placed over the patient's entry point with one hand and the other hand is used to grasp device 10 while manipulating cap 30 towards the closed position with the thumb of

the other hand. Thus, retraction with one hand is possible before the needle is removed from the patient.

As cap **30** is pivoted into a blocking position with respect to the opening **26**, protrusions **38** come in contact with back end **50**. As the thumb pushes cap **30** further into cavity **24**, movable member **40** moves forward along surface **94** toward front wall **14**. Annular stop **86** prevents retraction body **60** from moving forward with movable member **40**. Stop **86** disassociates retraction body **60** from the mouth of the movable member. Retraction body **60** is freed from front portion **54** of the movable member by relative movement between edge **64** and surface **56**. When retraction body **60** comes free, spring **77** acting on retraction body **60** then drives retraction body **60** backward carrying needle **88** into outer body **12**. Constriction **98** which constitutes a stepped in portion **100** of the wall of the movable member prevents retraction body from further rearward movement beyond the retracted position of FIG. **2**. Cap **30** completely closes the back of the outer body **12** in a friction fit. Coil spring **77** which closely circumscribes the tubular wall **66** of retraction body **60** tends to stabilize the retraction body as it is retracting so that it moves straight back without tilting. In the retracted position of FIG. **2**, the sharp needle points are entirely enclosed within outer body **12** and not accessible. The opening in hub **28** is too small to insert a finger and cap **30** prevents access from behind. Consequently, the danger from needle sticks during subsequent handling and disposal of this single use medical device are greatly reduced once the cap is closed. The device cannot be retracted without closing the cap. Once retracted, the device is not reusable without considerably effort.

In the best mode, it is anticipated that only about ⅛ of a pound needs to be generated by spring **77** in its fully compressed position since retraction body **60** is essentially free from restraint once it is dissociated from the mouth of the movable member. The outer body **12** in cap **30** can be molded as a single unit. Hinge **32** is preferably a so-called "living hinge" which is connected to the body **12** during the molding process. Body **12** would preferably come out of the mold with cap **30** in the orientation shown in FIG. **4**.

What is claimed:

**1**. A cap operated retractable medical device combination comprising:

a long thin walled tubular outer body having a back end with an opening and a front end which incorporates a centered hub;

an elongated movable member closely fitting entirely within the outer body, the movable member having a back end with an opening and a front end and front portion wherein the front portion has a radially enlarged inner surface and an outer surface;

a retraction body having a laterally extending wall with an outwardly facing edge, releasably held at a forward position with respect to the movable member by means of the radially enlarged inner surface of the front portion of the movable member;

the movable member being held in position with the retraction body adjacent the hub of the outer body by means of a tight area created between the outer surface of the front portion of the movable member and the inside surface of the wall of the outer body near its front end;

a cap hinged at the back end of the outer body and selectively movable between an open position and a closed position relative to the opening at the back end of the outer body, said cap having a cam surface